REMARKS

Claim 10 has been amended to specify that the claimed compound is "substantially purified." Support for this amendment may be found in the specification, for example, in paragraphs 0034 and 0035; a non-limiting example of preparing a substantially purified compound may be found at paragraphs 0049-0057.

As explained below, to expedite prosecution, Claims 11-13, 18, 23, and 25 have been amended to specify that the claimed colon cancer is an adenocarcinoma colon cancer. Support for these amendments may be found in the specification, for example, in paragraph 0113.

As explained below, to expedite prosecution, Claims 11, 12, 15, 20, 23, and 27 have been amended to specify that the claimed leukemia is a T-cell leukemia. Support for these amendments may be found in the specification, for example, in paragraph 0115.

Claims 14, 16, 19, 21, and 26 have not been rejected.

The Applicants have carefully considered all of the Examiner's rejections and respectfully submit that the claims are now fully in condition for allowance for at least the following reasons:

Rejection under § 102

The Examiner has rejected Claim 10 under 35 U.S.C. § 102(b) as being anticipated by the compound itself. The Examiner asserts that the microorganism "has always made the compound" and indicates that original Claim 10 is not directed to a purified or isolated compound. Applicants fail to appreciate how the undiscovered operation of the organism qualifies as prior art under § 102(b), as it cannot be considered a patent, printed publication, public use or offer for sale. Nonetheless, for purposes of § 101, discussed below, the Applicants have amended Claim 10 to be directed to a substantially purified compound. The Applicants respectfully submit, and the Examiner appears to acknowledge, that the subject matter of amended Claim 10 is novel and non-obvious.

Rejection under § 101 – Statutory Subject Matter

The Examiner has rejected Claim 10 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Examiner asserts that Claim 10 did not distinguish the compound over its naturally occurring form and indicates that the claim should be amended "to indicate the

hand of the inventor." Consistent with the Examiner's recommendation, the Applicants have amended Claim 10 to be directed to a substantially purified compound. The Applicants respectfully submit that the compound in substantially purified form is statutory subject matter.

Rejections under § 112

The Examiner has rejected Claims 11-13, 15, 18, 20, 22-25, and 27 under 35 U.S.C. § 112. The Examiner did not indicate the exact statutory grounds for the rejection, but the Applicants understand the basis of the rejection to be for lack of enablement. The Examiner asserts that that there are many diverse types of colon cancers and that "treatment greatly differs" between the types, but does recognize that adenocarcinomas and squamous cell cancers tend to be treated in the same fashion. Applicants note that § 112, ¶ 1 does not require present evidence of pharmaceutical *efficacy* against all cancers embraced by the claims. *See e.g.*, *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (noting that testing for effectiveness is properly left to the Food and Drug Administration). Nonetheless, to expedite prosecution, but not to prejudice further prosecution in continuation applications, Applicants have amended the claims such that they now recite adenocarcinoma colon cancers. The Applicants respectfully submit that they have fully enabled treatment of such cancers by their demonstration of efficacy against HT-20 human colorectal adenocarcinoma cells.

The Examiner further argues that there are many different types of leukemia and that no compound has been found "effective generally against leukemias." Applicants note that § 112, ¶ 1 does not require present evidence of pharmaceutical *efficacy* against all cancers embraced by the claims. *See e.g.*, *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (noting that testing for effectiveness is properly left to the Food and Drug Administration). Nonetheless, to expedite prosecution, but not to prejudice further prosecution in continuation applications, Applicants have amended the claims such that they now recite T-

cell leukemias. The Applicants respectfully submit that they have fully enabled treatment of such leukemias by their demonstration of efficacy against Jurkat human T-cell leukemia cells.

CONCLUSION

The Applicants respectfully submit that by the foregoing amendments and remarks they have overcome all of the Examiner's rejections and that the Application is fully in condition for allowance. Applicants therefore respectfully request that the Examiner issue a Notice of Allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 4, 2006

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